

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 15 is amended and claims 2 and 7-9 remain cancelled herein without prejudice. New claims 34-37 are added. Accordingly, by this Amendment, claims 1, 3-6 and 10 – 37 are pending in this application. No new matter has been added. Reexamination and reconsideration are respectfully requested.

In the Office Action dated March 14, 2005, the Examiner stated that claims 1, 3-6, 10, 11 and 23-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species. However, it is respectfully submitted that the withdrawal of claims 23-32 was in error and those claims should remain in consideration in the present patent application. In particular, the Examiner previously raised a restriction/election requirement in the Office Action dated November 4, 2004, in which the Examiner identified two inventions, as follows:

Invention I. Claims 1-11 and 33; and

Invention II. Claims 12-14, 15-28 and 29-32.

In response to that restriction/election requirement, Applicant submitted a written response and Amendment dated November 15, 2004, in which Applicant elected (provisionally and with traverse) the invention of group 2 (i.e., claims 12-32). Accordingly, all of claims 12-32 should be pending and under consideration in the present patent application. In addition, it is noted that claims 23-32 were included in the search and examination already conducted in connection with the first Office Action dated March 2, 2004. The withdrawal of claims 23-32 from consideration should, therefore, be reversed and those claims should be examined and under consideration in the present patent application as being part of the elected group 2 invention previously identified by the Examiner.

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by DiCarlo. This rejection is respectfully traversed in view of claim 15 as amended herein.

As amended, claim 15 is directed to a non-vascular implant system that includes, among other features, an implant unit to be implanted in a first area of a patient's body, a sensor configured to be disposed in a second area of a patient's body remote from the first area and a tool for creating a subcutaneous tunnel from the first area of the patient's body to the second area of the patient's body. As further recited in claim 15, the sensor is configured to be placed in the second area of the human body by passing the sensor through the tunnel without passing the sensor through a vascular system. In addition, the sensor in claim 15 is configured to be connected to the implant unit after the implant unit is implanted in the human body.

While DiCarlo describes an implantable device that includes a sensor and an electronics package, DiCarlo neither describes nor suggests that those components are implanted in first and second areas of the patient's body in conjunction with a tool for creating a subcutaneous tunnel from the first area to the second area of the patient's body. Furthermore, DiCarlo neither describes nor suggests a sensor configured to be placed in the second area of the human body by passing the sensor through the tunnel without passing the sensor through a vascular system. Accordingly, it is submitted that claim 15, as amended, is patentably distinguished over DiCarlo. The rejection of claim 15 is, therefore, respectfully traversed.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiCarlo in view of Klein et al. and Penner et al. This rejection is respectfully traversed.

In particular, claim 12 is directed to a "method for non-vascular implant of a sensor" that comprises, among other features, "directing a sensor into a body cavity and disposing the sensor in a location remote from an incision through which the sensor is directed without passing the sensor through a vascular system." (Underlines added for emphasis.)

As described in the present specification, initially, an incision is been made for an implant unit 10 to be implanted in a pocket in subcutaneous tissue. After that incision is made, a small tunnel may for the sensor 12 may be extended from the pocket, where the incision for the tunnel

is made remote from the final placement of the sensor 12. The sensor 12 may be tunneled through the subcutaneous tissue and fixed at a location remote from the incision. In this manner, a single incision may be made for an implanted pump, while the sensor 12 may be tunneled to a remote location from the incision. The sensor 12 may be connected to the implant unit 10 by an electrical lead 20 and connector 18, through the tunnel. (See present specification, e.g., at page 8, line 19 to page 9, line 7; and also page 9 line 28 to page 10, line 12.)

As described in the above-cited section of the present specification, “because the sensing element 22 of the sensor 12 is not located in the vicinity of the main incision that was made to insert the main implant unit 10, the difficulties associated with obtaining a signal from the sensing element 22 due to the trauma of the area are avoided.” Otherwise, trauma in the implant area can prevent sensing of physiological parameters, if the sensor is located in the area of trauma, such as in the vicinity of the implant incision (as described on page 2, lines 9-19 of the present specification).

The disclosure by DiCastro of an implant unit (e.g., electronics package 35) and a sensor (e.g., sensor 22a or 22b) connected thereto does not address the above-cited features of claim 12. Because DiCastro describes no special manner of implanting the implant unit and sensor, one of ordinary skill in the art would have considered conventional implant techniques in which a sensor is inserted within an incision made for the sensor (or for the combination of the implant unit and sensor) or the sensor is passed through a portion of the patient’s vascular system. Therefore, a method as recited in claim 12, including “directing a sensor into a body cavity and disposing the sensor in a location remote from an incision through which the sensor is directed without passing the sensor through a vascular system” is neither described nor suggested by DiCastro.

Neither the Klein et al patent nor the Penner et al. patent (alone or in combination) address the above distinction between claim 12 and the DiCarlo reference. The Klein patent was cited by the Examiner for disclosing suture holes (13) to attach an implanted device to body tissue and benefits of performing minimum incision sizes. However, Klein et al. neither disclose

nor suggest disposing a sensor remote from the incision without passing a sensor through a vascular system.

The Penner et al. patent was cited by the Examiner as demonstrating the challenges of attaching remote sensors to monitoring circuitry and using a wireless connection between a sensor and monitoring circuitry to eliminate the challenges of connecting control circuitry with remote sensors. The Examiner further stated that, based on the teachings of Penner, et al., modifying the DiCarlo apparatus with wireless capabilities that connect the sensors located in remote areas with monitoring systems would have been considered an obvious design choice. However, Penner et al. does not address the claimed feature of “directing a sensor into a body cavity and disposing the sensor in a location remote from an incision through which the sensor is directed without passing the sensor through a vascular system” (underlines added for emphasis).

While the Examiner argues that the use of Penner et al.’s wireless capabilities would allow DiCarlo’s sensor to be located remote from the monitoring system, neither of those references address the claim feature of disposing the sensor in a location remote from an incision through which the *sensor* is directed. In other words, DiCarlo’s sensor would have to be implanted (even if it were provided with a wireless communication capability). One skilled in the art would have considered conventional implantation techniques for implanting DiCarlo’s sensor. Because the DiCarlo and Penner et al. references (and the Klein et al reference) fail to describe or suggest implanting the sensor by “directing a sensor into a body cavity and disposing the sensor in a location remote from an incision through which the sensor is directed without passing the sensor through a vascular system” (underlines added for emphasis), none of those references alone or in combination renders the method of claim 12 unpatentable.

Claims 13 and 14 are dependent on claim 12 and, therefore, are patentably distinct from the cited references at least for reasons as discussed above with respect to claim 12. Accordingly, the rejection of claims 12-14 is respectfully traversed.

Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiCarlo in view of Klein, et al. and Penner, et al. and in further view of Ellinwood, Jr., Lewis et al. and

Blackshear et al. This rejection is respectfully traversed, at least for reasons as discussed above with respect to independent claim 15.

In particular, claims 16-22 are dependent (directly or indirectly) on claim 15. Claim 15, as amended herein, is patentably distinguished over the DiCarlo reference, as discussed above. Neither Klien et al., Penner et al., Ellinwood, Jr., Lewis et al. or Blackshear et al. address the above-noted distinctions between claim 15 and the DiCarlo reference. In particular, none of the Klien et al., Penner et al., Ellinwood, Jr., Lewis et al. or Blackshear et al. references describes or suggests an implant unit and a sensor implanted in first and second respective areas of the patient's body in conjunction with a tool for creating a subcutaneous tunnel from the first area to the second area of the patient's body. Furthermore, none of the Klien et al., Penner et al., Ellinwood, Jr., Lewis et al. or Blackshear et al. references describes or suggests a sensor configured to be placed in the second area of the human body by passing the sensor through the tunnel without passing the sensor through a vascular system. Accordingly, it is submitted that claim 15, as amended, is patentably distinguished over DiCarlo, Klien et al., Penner et al., Ellinwood, Jr., Lewis et al. or Blackshear et al., alone or in combination. Because dependent claims 16-22 are dependent (directly or indirectly) on claim 15, the same distinctions noted above with respect to claim 15 apply to claims 16-22 as well. The rejection of claim 16-22 is, therefore, respectfully traversed.

While the Examiner stated that claims 29-32 were withdrawn from consideration, as noted above, those claims should be pending and under consideration in the present application as being included in the elected group of claims. Those claims are believed to be patentably distinguished over the cited references. For example, claim 29 recites a method for non-vascular implant of a sensor which includes, among other features, "creating a tunnel in subcutaneous tissue," "directing the sensor through the tunnel" and "connecting the sensor to the implant unit." Claims 30-32 relate to creating a tunnel using a blunt instrument (claim 30) which, in claim 32, is specified as a trocar. Neither DiCarlo, Klein et al. nor Penner et al. describe or suggest the creation of a tunnel and directing a sensor through the tunnel. Furthermore, those references do not describe or suggest using a blunt instrument or trocar to create a tunnel through which a

sensor is directed. Accordingly, claims 29-32 are believed to be patentably distinguished over the references of record.

New claims 34-37 are added to further protect aspects of the invention. Each of those claims is believed to be patentably distinguished over the prior art of record. In particular, new claims 34-37 are dependent (directly or indirectly) on independent claim 12. Accordingly, distinctions discussed above with respect to claim 12 apply to claims 34-37, as well. In addition, each of claims 34-37 recites further distinguishing features. For example, claim 34 recites that incising an area remote from a sensor location comprises creating a tunnel extending from the area incised for inserting the implant unit. New claim 35 recites that connecting the sensor to the implant unit comprises extending electrical leads through the tunnel. New claim 36 recites that incising an area remote from a sensor location comprises tunneling an introducer from the area incised for inserting the implant unit, through subcutaneous tissue, to an area remote from the area incised for inserting the implant unit. New claim 37 recites that connecting the sensor to the implant unit comprises extending electrical leads through a tunnel formed in the subcutaneous tissue by said tunneling. Because the cited references do not disclose or suggest tunneling between an area for implanting an implant unit and another area for implanting a sensor, the cited references do not disclose or suggest the further features relating to such tunneling or the resulting tunnel as recited in claims 34-37.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check

being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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